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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,783	08/21/2003	Nancy C. Lan	1483.0370003	6918

26111 7590 12/13/2005

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,783	LAN, NANCY C.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/21/03 & Tele. Interview on 11/25/05* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-52* is/are pending in the application.

4a) Of the above claim(s) *22-33 and 46-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21,34-45 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/25/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: (i) a first agent selected from carbamazepine, lamotrigine and 4-(4'-fluorophenoxy)-benzaldehyde semicarbazone and (ii) a second agent selected from gabapentin and pregabalin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10-21, 40, 50-52 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with John M. Covert on November 25, 2005 a provisional election was made to prosecute the 4-(4'-fluorophenoxy)-benzaldehyde semicarbazone and gabapentin as the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-33 and 46-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10-21,34-45 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (WO 9847869) in view of Bryans et al. (Medicinal Research Reviews, 1999,

19(2) 149-77), and if necessary, further in view of Applicant's admitted prior art (page 3, line 10 thru page 4, line 5 of the specification) and Singh (US 6001876).

The claims read on use of a pharmaceutical composition comprising a sodium channel blocker such as 4-(4'-fluorophenoxy)benzaldehyde semicarbazone in combination with gabapentin for the treatment, prevention or amelioration of chronic pain, more specifically "trigeminal neuralgia", "diabetic neuropathy" and "cancer pain".

Wang teaches the use of 4-(4'-fluorophenoxy)benzaldehyde semicarbazone for ameliorating chronic pain, neuropathic pain such as trigeminal neurologia or diabetic neuropathy (abstract; page 1 line 15 thru page 2, line 22; page 3, lines 27-28; page 4, line 4; page 25, lines 13-14; claims 1, 5, 7-8). Wang also teaches the use of sodium channel blocker (e.g., carbamzepine and lamotrigine) for treating neuropathic pain due to trigeminal neurologia and diabetic neuropathy (page 2, lines 5-22).

Bryans teaches the use of gabapentin for treating chronic pain, convulsion and behavioral disorder.

Applicant's admitted prior art discloses that " Gabapentin, an anticonvulsant with unknown mechanism of action has been shown recently to be efficacious for treating chronic pain (Rowbotham et al., JAMA 280: 1827-1842 (1998) and Backonja et al., JAMA 280:1831-1836 (1998))"(page 3, lines 26-29); and "Pregabalin is a potent follow-up compound to gabapentin. The compound has similar activity to gabapentin and is currently under clinical trials for neuropathic pain (SCRIP 2330:8 (1998))" (page 4, lines 3-5).

Singh teaches the use of pregabalin which has similar activity to gabapenin for the treatment of chronic pain including neuropathic pain, cancer pain and trigeminal neuralgia pain (Results; claims).

The teaching of Wang differs from the claimed invention in the combination use of sodium channel blocker such as 4-(4'-fluorophenoxy) benzaldehyde semicarbazone and gabapentin in treating chronic pain, namely "trigeminal pain", "diabetic neuropathy" and "cancer pain".

To incorporate such teaching into the teaching of Wang, would have been obvious in view of Bryans who teaches the use of gabapentin for treating chronic pain.

The above references in combination make clear that the sodium channel blocker (i.e., 4-(4'-fluorophenoxy)benzaldehyde semicarbazone) and gabapentin have been individually used for the treatment of chronic pain. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

One having ordinary skill in the art would have been motivated to modify the teaching of Bryans such that the pharmacological activity of gabapentin would be enhanced by the addition of sodium channel blocker such as 4-(4'-fluorophenoxy)benzaldehyde semicarbazone while toxicity associated with high dose of gabapentin would be minimized by the combination of said sodium channel blocker. One having ordinary skill in the art would have expected that the

claimed combination would be useful in treating chronic pain due to trigeminal neuralgia and diabetic neuropathy in view of combination of Wang and Bryans. Although the references are silent about the total effective amount of the combination in treating "trigeminal pain", "diabetic neuropathy" and "cancer pain", such determination of optimal ranges of effective amounts of each component is well considered within the skill of the artisan, absent evidence to the contrary.

Conclusion

4. No Claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614